FDA Report to PharmPAC
January 4, 2007
Compiled by CDR Matthew Tarosky, Pharm.D., U.S.P.H.S.

- Senate approved Dr. Andrew von Eschenbach as FDA Commissioner: http://www.fda.gov/oc/voneschenbach/bio.html
- Susan Winkler, RPh, Esq., previous Vice President for Policy and Communication and Staff Counsel for American Pharmacists Association, has been appointed as FDA Chief of Staff.
- FDA celebrated its first 100 years in 2006. It is unclear what impact the new Democratic Congress will have on FDA, but possible impact could include an independent drug safety office, reauthorization of user fees, and generic biologics. FDA is developing policies and issuing new regulations and guidance documents for using epidemiologic data to improve drug-safety assessments; making the review and approval of generic drugs more efficient; and assessing use of industry user fees to evaluate and regulate direct-to-consumer (DTC) drug advertising.
- To receive timely safety information from FDA, please consider joining the MedWatch listserv, by visiting and subscribing to the NIH Listserv
- Please visit FDA's Free E-mail lists to sign up for important information on various topics related to recalls, press releases, etc.
- For New Drug Approvals search Drugs@FDA
- FDA is proposing significant regulatory changes that would make experimental drugs more widely and easily available to seriously ill patients with no other treatment options. In addition, another proposed rule would clarify when it is appropriate to charge for an experimental drug. FDA Deputy Commissioner for Operations Dr. Janet Woodcock stated that "FDA hopes this proposal will increase awareness in the health care community of the range of options available for obtaining experimental drugs for seriously ill patients. By clarifying and streamlining the processes, FDA also hopes to encourage companies to make such drugs available, and reduce barriers for health care practitioners in obtaining them."
    - FDA Proposed Rule on Expanded Access to Investigational Drugs for Treatment Use
    - FDA Proposed Rule on Charging for Investigational Drugs
- Avoid using quinine for treating leg cramps. Since 1969, FDA has received 665 reports of serious adverse events with quinine use, including 93 deaths. Since quinine is association with cardiac arrhythmias, thrombocytopenia, and severe hypersensitivity reactions, the use of quinine should be extremely limited. Mutual Pharmaceuticals' quinine is approved for malaria and includes a caution against use for leg cramps.